

## **REMARKS**

### **I. Overview**

Claims 30 and 35 have been amended. Support for these amendments can be found throughout the specification, for example, at page 8, lines 19-29, page 28, lines 6-16, and page 30, lines 17-22. No new matter has been added. Claims 1-29, 31-34, and 36-37 have been cancelled. Applicants retain the right to pursue the subject matter of the cancelled claims in one or more continuing applications. Upon entry of this amendment, claims 30 and 35 are pending. The present response is an earnest effort to place all claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

### **II. Claim Rejections under 35 U.S.C. § 101**

Claims 30-37 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Examiner states this rejection has been necessitated due to claim amendments.

Accordingly, Applicants have amended claim 30 to recite "an isolated group 2/3 allergen". Dependent claims 35 is similarly amended. Claims 31-34 and 36-37 have been cancelled. In light of the above, Applicants respectfully request that the rejection be withdrawn and respectfully submit that the claims 30 and 35 are in form for allowance.

### **III. Claims Rejections Under 35 U.S.C. § 112**

Claims 30-37 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A. Claim 30 is rejected under 112, second paragraph, as allegedly being indefinite in its recitation "carrier", which the Examiner states is confusing, since it is unclear which "carrier" is being referred to.

While not acquiescing to the Examiner's arguments, Applicants have amended the claims to remove the phrases "carrier" from claim 30.

B. Claim 36 is rejected under 112, second paragraph, as allegedly being indefinite in its recitation "preparation further includes  $\beta$ -expansin", which the Examiner states is confusing since it is unclear how a protein preparation comprising a group 2/3 pollen allergen with  $\beta$ -expansin activity further comprises another  $\beta$ -expansin protein.

As an initial matter, Applicants have cancelled claim 36. Applicants disagree with this rejection as applied to amended claim 30. Claim 30 now recites "an isolated group 2/3 pollen allergen of SEQ ID NO:2 having  $\beta$ -expansin activity and an isolated  $\beta$ -expansin having  $\beta$ -expansin activity, wherein said  $\beta$ -expansin is not a group 2/3 allergen, and wherein the group 2/3 pollen allergen and the  $\beta$ -expansin in combination synergistically expand monocot cell walls." Applicants respectfully submit that the specification at page 28, lines 6-16, and page 30, lines 17-22, makes clear that one skilled in the art would be able to identify  $\beta$ -expansins that are not group 2/3 allergens that have beta-expansin activity. In light of the above, Applicants respectfully request that the rejection be withdrawn and respectfully submit that the claims are clear and in form for allowance.

#### **IV. Claim Rejections Under 35 U.S.C. § 112**

##### **A. Enablement**

Claims 30-37 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated group 2/3 allergen from grass pollen encoding a polypeptide as defined in SEQ ID NO:2, allegedly does not reasonably provide enablement for any other group 2/3 allergen.

The Examiner states it is important to note that claim 30 encompasses any group 2/3 pollen allergen from any source and claims 32-33 and 35 further encompass any group 2/3 pollen allergen with expansin activity. The Examiner states the claims further encompass any group 2/3 pollen allergen that participates in plant cell wall extension function. The Examiner states Sampedro et al. teachings clearly indicate existence of group 2/3 pollen allergen lacking expansin activity, and cites the reference to support the implication that such group 2/3 pollen allergen would not be expected to participate in cell extension functions as encompassed by the claims.

Applicants respectfully disagree. One of skill in the art would be able to make and use the present invention without undue experimentation using well known techniques available prior to the priority filing date of the present application.

As amended, claim 30 requires, "an isolated group 2/3 pollen allergen of SEQ ID NO:2 having  $\beta$ -expansin activity and an isolated  $\beta$ -expansin having  $\beta$ -expansin activity wherein said  $\beta$ -expansin is not a group 2/3 allergen, and wherein the group 2/3 pollen allergen and the  $\beta$ -expansin in combination synergistically expand monocot cell walls". Applicants respectfully submit that those of ordinary skill in the art would be familiar with routine techniques and standards of determining beta expansin activity. Pages 25-27 of the specification describe the

purification and identification of a group 2/3 allergen of SEQ ID NO:2 having beta expansin activity and a  $\beta$ -expansin that is not a group 2/3 allergen having beta-expansin activity.

In response to the Examiner's argument that the related art is unpredictable, Applicants respectfully remind the Examiner that enablement does not require that all encompassed embodiments be operative but rather that one skilled in the art can identify operative embodiments without engaging in undue experimentation. MPEP § 2164.06. There is no requirement that every possible combination of group 2/3 allergen and  $\beta$ -expansin act synergistically on expanding monocot cell walls. The Federal Circuit has held that claims may encompass some inoperative species, so long as the number of inoperative species does not become significant and force one of ordinary skill in the art into undue experimentation in order to practice the invention. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984). Furthermore, Applicants have provided teachings that guide one of ordinary skill in the art in making and assessing the functional activities of group 2/3 allergens of SEQ ID NO:2 and additional  $\beta$ -expansins.

Testing the group 2/3 allergen or other  $\beta$ -expansin polypeptide or protein sequences for beta expansin activity is straightforward and known to one skilled in the art. Furthermore, ample guidance is provided in the specification. In particular, the examples in the specification at pages 27-30 describe cell wall expansin and relaxation assays which would be able to be easily performed by one skilled in the art. Thus, one of ordinary skill in the art reading the specification would be able to follow the teachings and would be, therefore, placed in possession of all information needed to make a solution comprising a group 2/3 allergen and a  $\beta$ -expansin, which is not a group 2/3 allergen, having beta expansin activity for expanding monocot cell walls.

In light of the above, Applicants submit that claims 30 and 35 are fully enabling and commensurate in scope with the disclosure of the claimed invention. Claims 31-34 and 36-37 have been cancelled. Therefore, Applicants request that the rejections under 35 USC §112 be withdrawn and reconsidered. Applicants respectfully submit that the claims are in form for allowance.

**B. Written Description**

1. Claims 30-37 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states Applicants have failed to describe structures of their broadly claimed genus and correlate said structures to the function of plant cell wall expansion. The Examiner states, more importantly, Applicants have failed to describe functional conserved domains shared among the undisclosed structures of their broadly claimed genus.

Applicants respectfully traverse this rejection as applied to amended claim 30. The written description standard as applied is improper. As an initial matter, Applicants have amended claim 30 to recite "an isolated group 2/3 pollen allergen of SEQ ID NO:2 having  $\beta$ -expansin activity and an isolated  $\beta$ -expansin having  $\beta$ -expansin activity, wherein said  $\beta$ -expansin is not a group 2/3 allergen, and wherein the group 2/3 pollen allergen and the  $\beta$ -expansin in combination synergistically expand monocot cell walls". Support for this amendment may be found throughout the specification, for example, page 8, lines 19-29, page 28, lines 6-16, and page 30, lines 17-22.

The written description requirement may be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e.,

complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Applicants have provided a relevant identifying characteristic – the structure of a group 2/3 allergen, that is SEQ ID NO:2, and a physical property of the group 2/3 allergen -- having  $\beta$ -expansin activity and expanding monocot cell walls synergistically with a  $\beta$ -expansin having beta-expansin activity that is not a group 2/3 allergen. The specification provides detailed guidance to one skilled in the ordinary art to make, isolate, and identify group 2/3 allergens and additional  $\beta$ -expansins and test these proteins for beta expansin activity. The specification also provides specific guidance of how to test these proteins for the functional characteristic of their ability to expand cell walls. Therefore, one skilled in the art would be able to easily test group 2/3 allergens of SEQ ID NO:2 and other  $\beta$ -expansins proteins for this activity.

Because Applicants have provided a structure (sequence) encompassed by a group 2/3 allergen (SEQ ID NO:2) and methods of assaying for beta expansin activity and monocot cell wall extension, Applicants submit that support has been provided for the full scope of the claims. In light of the above, Applicants request that the rejection to claims 30 and 35 be withdrawn and reconsidered. Claims 31-34 and 36-37 have been cancelled. Applicants respectfully submit that the claims are in form for allowance.

2. Claims 30-37 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states the claims contain subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states claims 30-37 recite "protein preparation" which introduces NEW MATTER into amended claims. The Examiner states claims 30 and 37 recite "carrier" which introduces NEW MATTER into amended claims. The Examiner states claim 37 recites "buffer" which introduces NEW MATTER into amended claims. Claim 37 has been cancelled.

While not acquiescing to the Examiner's arguments, Applicants have amended the claims to remove the phrases "carrier" and "protein preparation" from claims 30 and 35. Claim 31-34 and 36-37 have been cancelled. In light of the above, Applicants respectfully request that the rejection be withdrawn and respectfully submit that the claims are in form for allowance.

#### **V. Claim Rejections Under 35 U.S.C. § 102**

Claims 30-37 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ansari et al. (Biochemistry, 28:8665-8670, 1989) and evidenced by Marino et al. (Structure, 7:943-952, August 1999) for the reasons of record stated in the Office Action mailed April 4, 2006 as applied to claims 6-7 and 13-21, now cancelled.

The Examiner states Ansari et al. clearly disclose protein preparation comprising a group 2/3 pollen allergen from rye grass. The Examiner states the reference further teaches that the protein preparation comprises a polypeptide having an amino acid sequence which is 100% identical in sequence to instant SEQ ID NO:2, wherein first 20 amino acids at N-terminal end of said protein comprises a sequence which is 100% identical to SEQ ID NO:5. The Examiner maintains that the property of cell expansion due to  $\beta$ -expansin activity is inherent to the amino acid sequence taught in the reference.

Applicants traverse this rejection. The test for anticipation is whether the single piece of prior art discloses "every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Claim 30 has been amended so that it now recites "an isolated group 2/3 pollen allergen of SEQ ID NO:2 having  $\beta$ -expansin activity and an isolated  $\beta$ -expansin having  $\beta$ -expansin activity, wherein said  $\beta$ -expansin is not a group 2/3 allergen, and wherein the group 2/3 pollen allergen and the  $\beta$ -expansin in combination synergistically expand monocot cell walls". Accordingly, Ansari et al. fail to teach the limitations of claim 30 as amended because there is no teaching of a solution comprising a group 2/3 allergen of SEQ ID NO:2 and another  $\beta$ -expansin where the combination synergistically expand monocot cell walls. Thus, Ansari et al. cannot anticipate the instant invention. Claim 35 dependent on claim 30 is not anticipated for at least the reasons argued above, plus the elements in the claim.

Not only does Ansari et al. not teach the combination of the group 2/3 allergen and a  $\beta$ -expansin that is not a group 2/3 allergen, at the time the article by Ansari et al. was published, it was not known that group 2/3 allergens and other  $\beta$ -expansins could be used to expand monocot cell walls, much less act synergistically for this purpose. Thus, Ansari et al. cannot anticipate the instant invention. For at least the reasons above, Applicants respectfully request that the rejection be withdrawn and respectfully submit that the claims are in form for allowance.

## **VI. Conclusion**

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.



Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "Janae E. Lehman Bell". The signature is fluid and cursive, with the first name "Janae" being the most prominent.

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